

PD6 Exh 4

# Corporate Security & Regulatory Affairs (CSRA)

Chris Zimmerman,

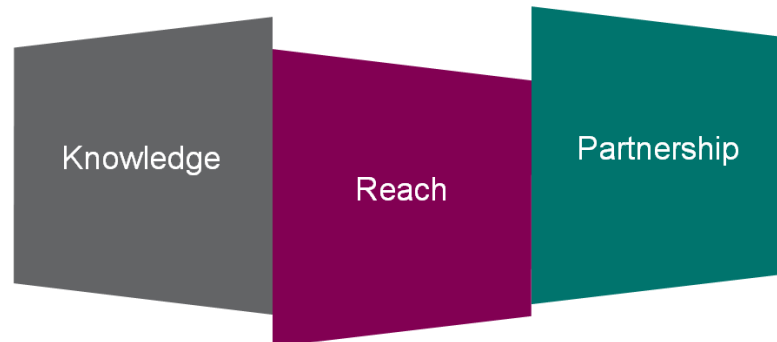
Vice President, CSRA & Chief Compliance Officer

December 12, 2016



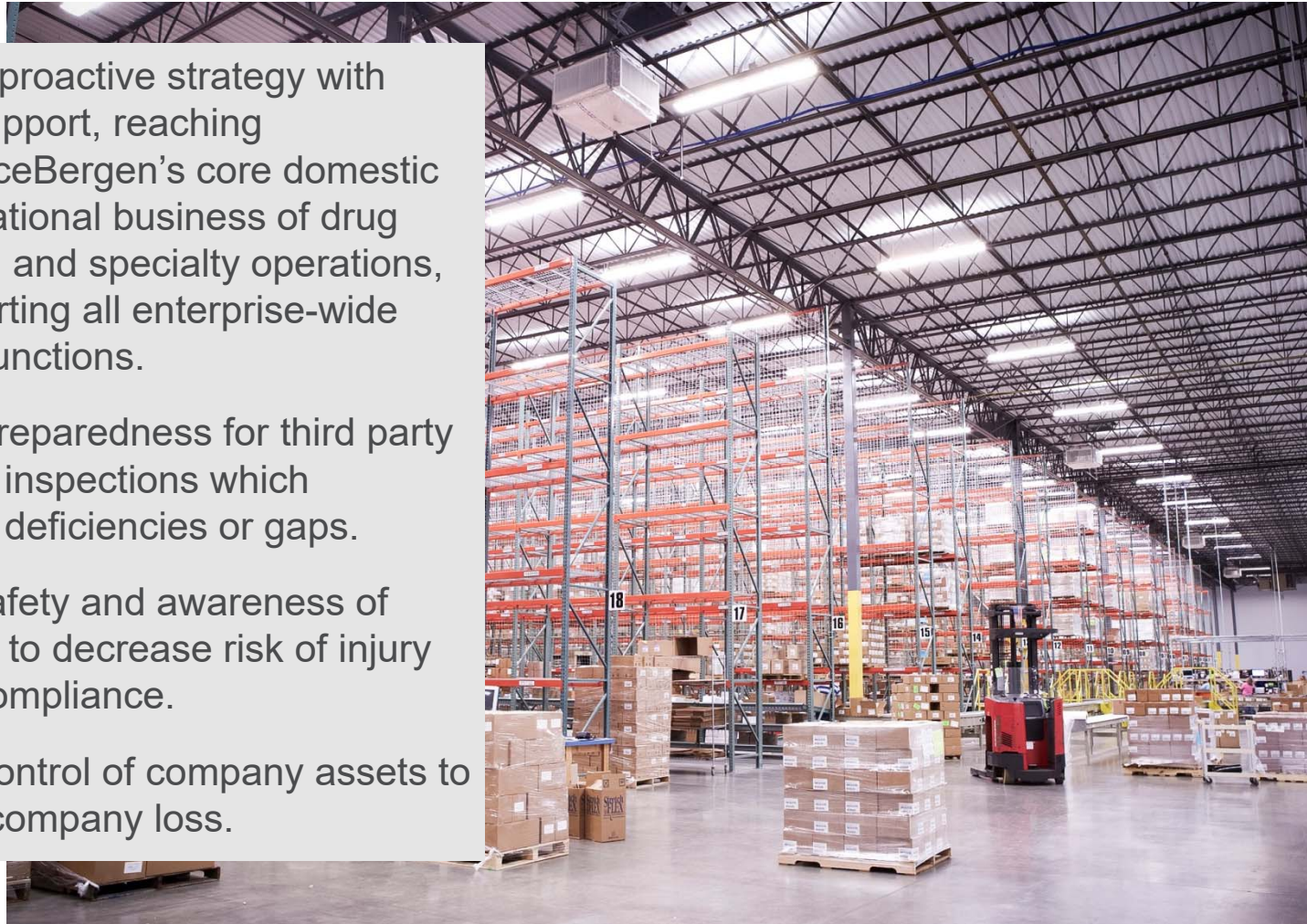
## CSRA Mission Statement

- Leverage knowledge, reach and partnership to establish and maintain a culture of compliance throughout AmerisourceBergen Corporation and its business units.
- Promote education, prevention, detection and resolution of instances of conduct that are not compliant with all applicable federal, state, local and international law, regulation requirements, contract requirements accreditation, and corporate policies and procedures.
- Provide a safe workplace for all employees, protect company assets and ensure measures are taken for patient safety.
- Provide crisis and business continuity management throughout ABC.



## CSRA Purpose

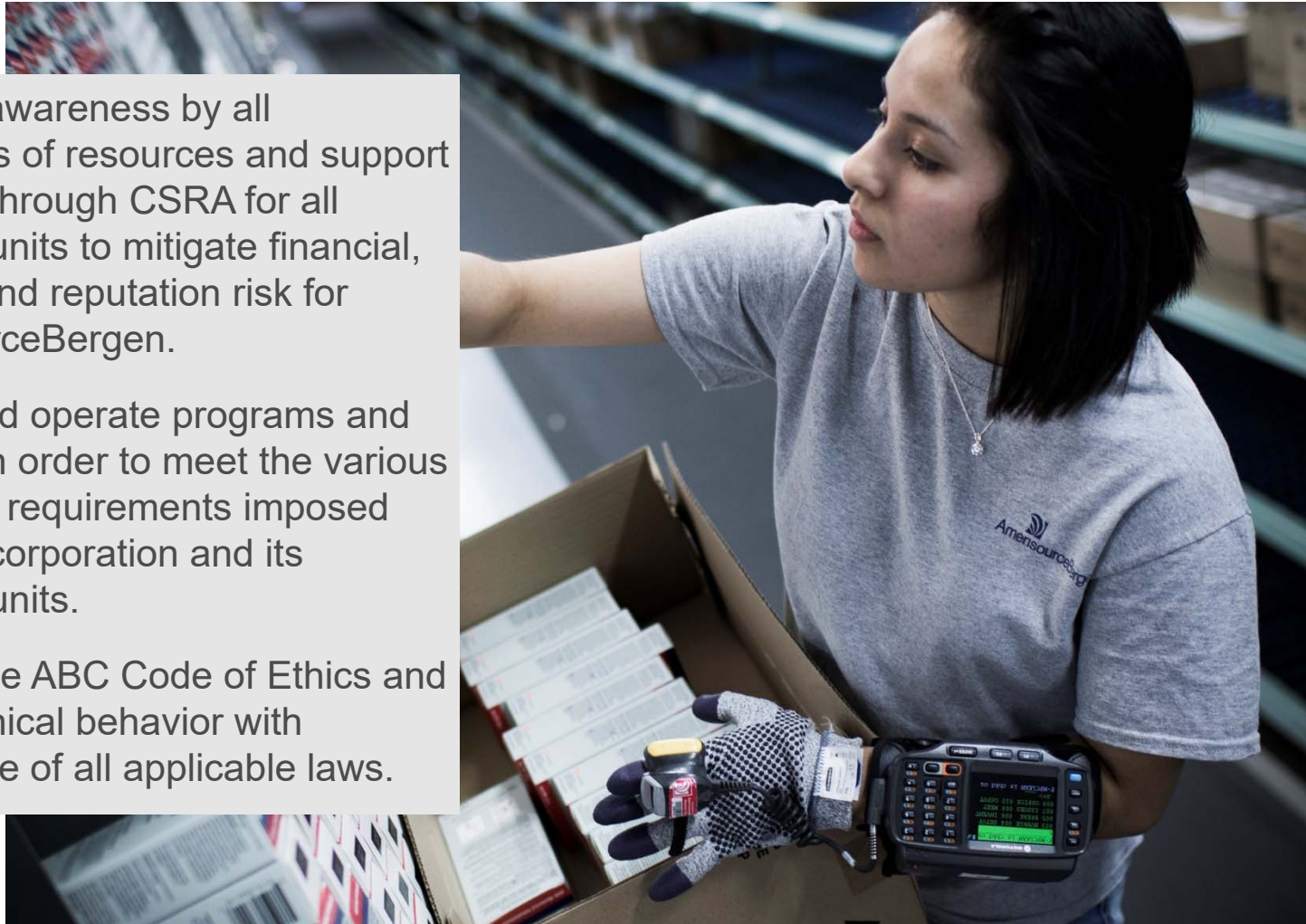
- Practice a proactive strategy with reactive support, reaching AmerisourceBergen's core domestic and international business of drug distribution and specialty operations, and supporting all enterprise-wide business functions.
- Increase preparedness for third party audits and inspections which decreases deficiencies or gaps.
- Improve safety and awareness of associates to decrease risk of injury and non-compliance.
- Increase control of company assets to decrease company loss.





## CSRA Purpose

- Increase awareness by all employees of resources and support available through CSRA for all business units to mitigate financial, physical and reputation risk for AmerisourceBergen.
- Design and operate programs and systems in order to meet the various regulatory requirements imposed upon the corporation and its business units.
- Enforce the ABC Code of Ethics and ensure ethical behavior with compliance of all applicable laws.



## Authority

- The Security and Regulatory Affairs (CSRA) Department Compliance program is administered under the authority of the AmerisourceBergen Legal department, and supports:
  - The Office of Compliance
  - The Code of Conduct and Business Ethics
  - Federal/State/Local law, regulation and accreditation
  - Company policies and procedures
  - Contractual requirements
- CSRA also takes direction from three executive committees:
  - The ABC Board of Directors, Audit and Corporate Responsibility Committee
  - The ABC Ethics Committee
  - The ABC Risk Committee



## Department Overview

- Through this structure of coverage, the department leadership is provided through the Vice President of CSRA and the senior directors, known as the Executive Leadership Team:

Chris Zimmerman, VP & Corporate Compliance Officer

Steve Mays, Sr. Director - Distribution

David May, Sr. Director – Diversion Control & Federal Investigations

Paul Ross, Sr. Director - Specialty

Bruce Gundy, Director – Investigations

Ed Hazewski, Director – Security Services

### SCOPE:

CSRA provides regulatory compliance oversight and security assistance to all AmerisourceBergen operating units.

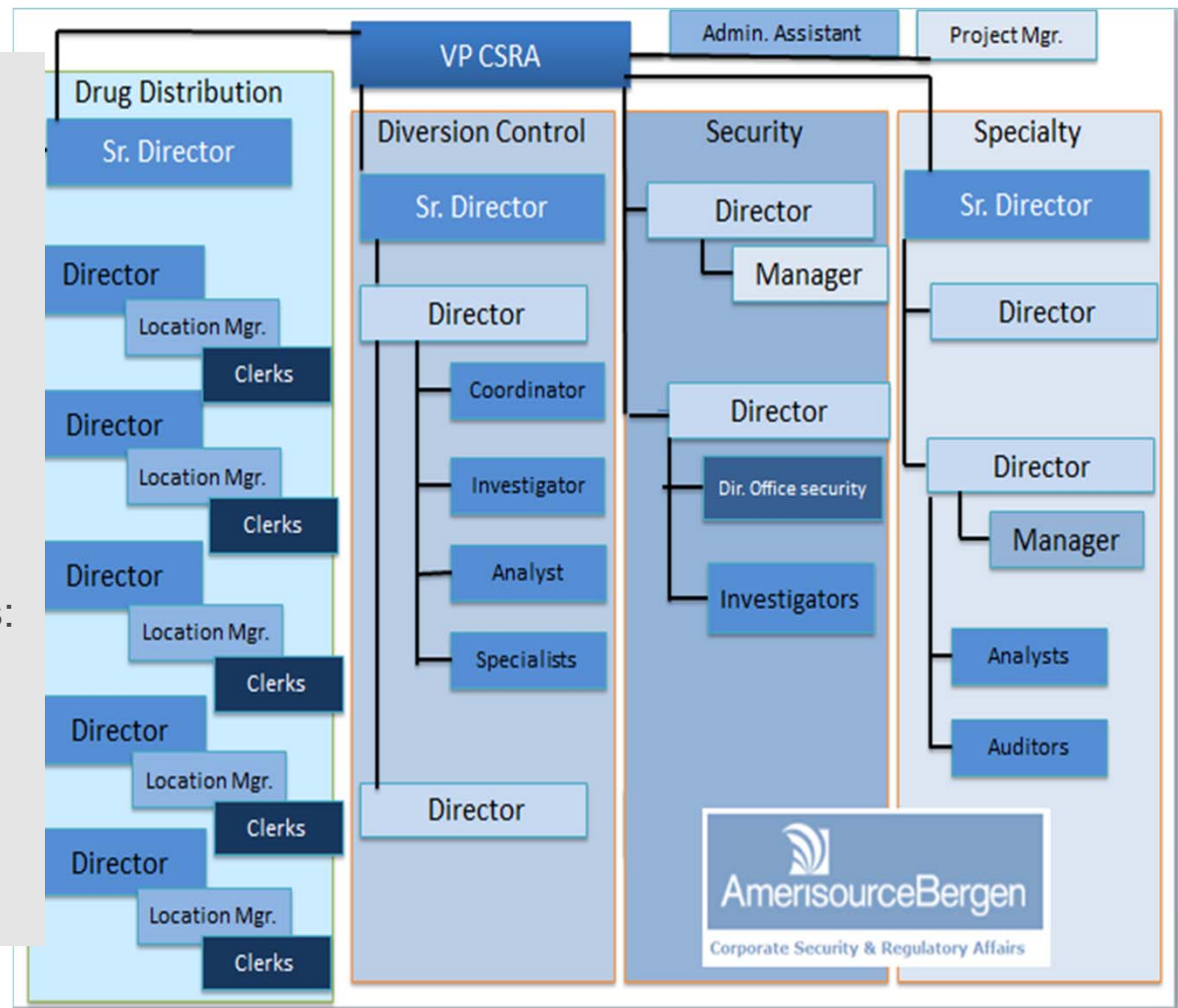
### Out of Scope:

CSRA does not provide oversight for the following areas and domains:

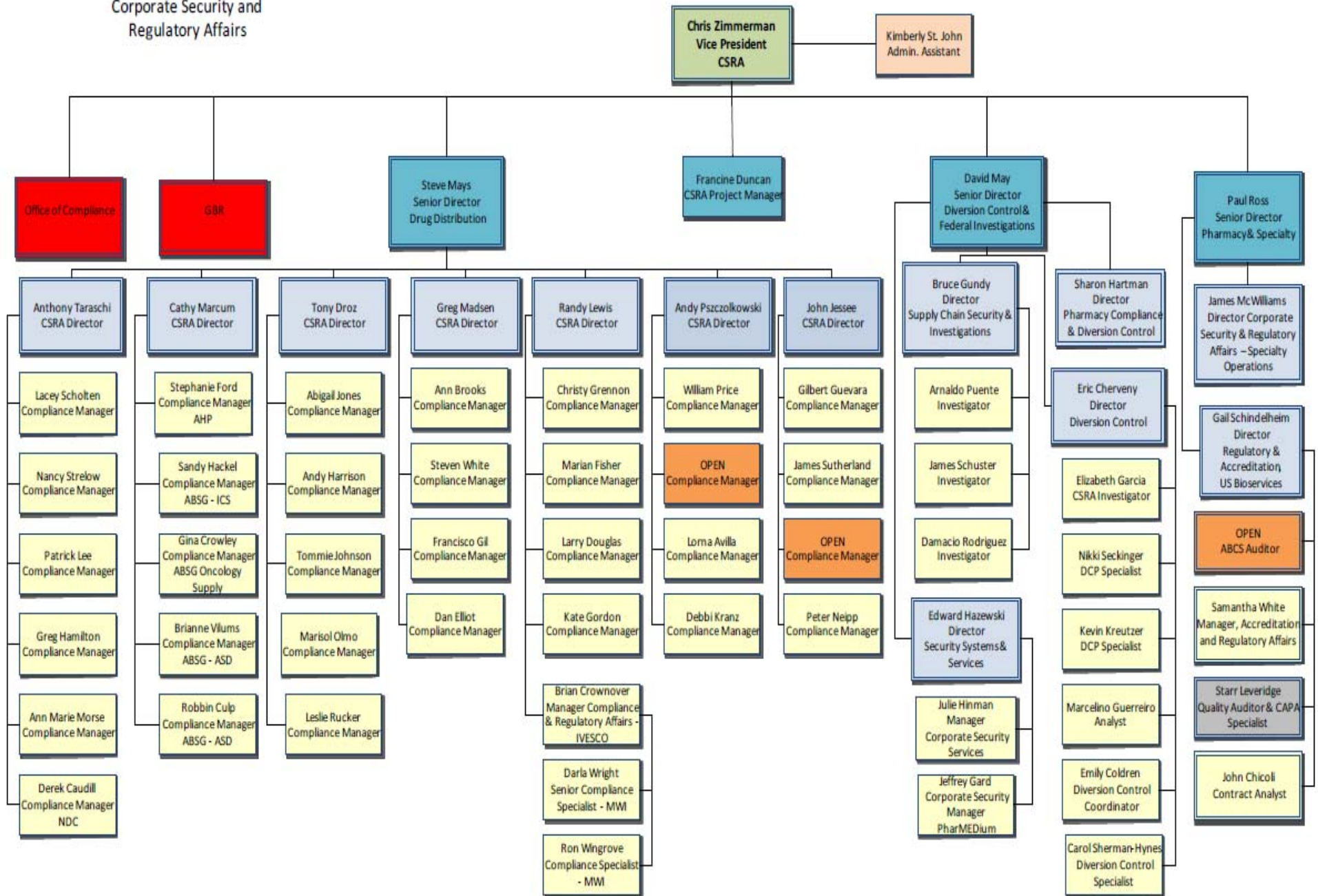
- Compliance related to Good Manufacturing Practices (GMP)
- Workers' compensation claims
- Quality Management activities
- Information protection and cyber security
- HIPAA
- Department of Transportation

## Department Overview

- CSRA is a multidisciplinary team with subject matter experts in pharmaceutical distribution, pharmacy, security, drug enforcement, quality, project management, clinical services, consulting and transportation.
- The department structure is primarily divided into sections:
  - Regulatory Compliance
  - Diversion Control
  - Security / Investigations
  - Other / Non-Regulatory Compliance





Corporate Security and  
Regulatory Affairs

## Overview

### Major CSRA Responsibilities – Regulatory Affairs

- Provide Regulatory and Security Oversight and Assistance to ABC Operating Units
- Conduct Compliance Audits and Reviews of all ABC Operating Units; certain ABC vendors (e.g., third party returns, carriers, etc.); and select ABC customers
- Monitor State & Federal Regulatory Activity
- Provide Support and Oversight During State and Federal Inspections/Audits/Information Requests
- Provide Accredited Regulatory and Security Training for ABC Associates and Customers
- Partner with other Corporate departments to create and implement policies and procedure (e.g., Operations – Cold Chain; Internal Audit – Inventory Adjustments; Risk Management – OSHA; Human Resources – Work Place Violence/Harassment; etc.)

## Overview

### Major CSRA Responsibilities – Corporate Security

- Investigations
- Crimes against the company
- Ethics/Policy violations
- Security Systems & Services
- Security Related Programs
- Business Continuity
- Inventory Protection
- Contract Diversion
- Oversee Carrier Evaluations
- Global Positioning System (GPS) Program
- Network Hotline
- Criminal Screening
- Training: Associates, Customers, Suppliers, Regulators
- Business Continuity Program

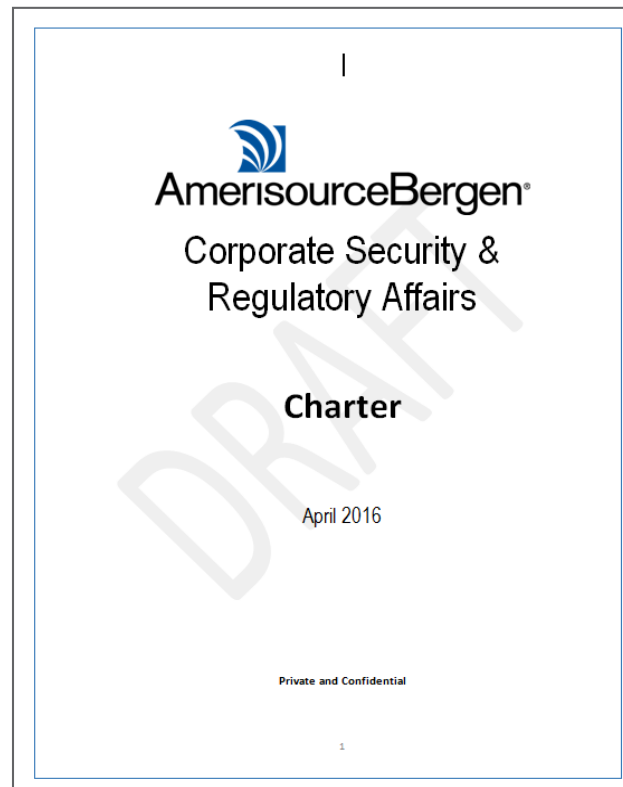
## Overview

### Major CSRA Responsibilities – Diversion Control Program

- New Customer Due Diligence
- Order Monitoring Program
- Threshold Reviews
- Continuous Customer Due Diligence
- Customer Actions
- Education and Training

## Program Development – Charter & Supporting Documents

- CSRA has developed a charter and supporting documents delineating the department's purpose, focus, roles and responsibilities.
- The framework for the business requirements and software configuration for the Matter Management System are derived from the Charter and its supporting documentation.



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This document is maintained on:  
S:\Departments\CSRA\CSRA Program Document Project 2016



## CSRA Objectives

- Clearly define the scope of CSRA functions and responsibilities within ABC, and those functions “out of scope” that CSRA does not perform.
- Support consistent delivery of services throughout the enterprise.
- Improve understanding of CSRA and set customer expectations around the department’s role.
- Specifically identify the functions CSRA provides for each business unit, which can vary.
- Create a system for centralized, consistent collaboration, workflow and documentation.
- Strengthen the effectiveness of CSRA’s relationship with its customers and partners throughout ABC.
- Advise executive management on the level of risk for each business unit and help CSRA better allocate resources and expenses.
- Provide a basis for consistent messaging when preparing training and communications materials.

# Program Development – Charter & Supporting Documents

- In addition to the Charter, supporting documents define CSRA Roles and Responsibilities by:
  - Business Unit
  - Functional Area
  - Individual Management Associate

**AmerisourceBergen**  
Corporate Security & Regulatory Affairs

CSRA – SPECIALTY GROUP ASSIGNMENTS

**DRAFT**

Specialty Group Responsibility Grid and Business Unit Risk Assessment:

Low Risk	Medium Risk	Moderate Risk	High Risk
<b>Paul</b>	<b>James</b>	<b>Gail</b>	
Develop and foster an environment of corporate regulatory compliance and quality through auditing and oversight			
<b>Xrenda</b>	<b>World Courier</b>	<b>USBio / Igti</b>	
FCRA (consulting with Mfr.) Anti-bribery/corruption training Sunshine Act compliance No CSRA staff on site Hold Accreditation	FCRA – Anti-bribery/corruption – (WC QA training, questionnaire support & 3 <sup>rd</sup> party vendor screening) Vendor Compliance Internal security issues No CSRA on site	PHI / HIPAA Pharmacy BOP compliance National licensing DEA / CS Reporting Claims – gov't payers 4 Accreditations	
<b>PHS / AdvRx</b>	<b>World Courier Ground</b>	<b>LASH / LASH Clinical</b>	
PHI / HIPAA Diversion Claims/Billing No CSRA on site	Diversion with drivers Accelerated expansion of svcs. No CSRA on site	PHI / HIPAA Non-dispensing Pharmacy license BCP Accreditation High risk employee pool / practice No CSRA on site	
<b>Good Neighbor Pharmacy</b>	<b>Innomar- 3PL/DC</b>	<b>LASH / Premier Source</b>	
PHI / HIPAA Anti-voidback	Compliance to license verification process No CSRA on site	PHI / HIPAA 3 <sup>rd</sup> party Submission claims gov't payers Lack of internal processes	
<b>MWI – Pharmacy</b>			
No claims/ cash-billing Pharmacy BOP compliance Licensing			
<b>COSTCO</b>			
CS Diversion – very low GI volume			

**CSRA Drug Distribution Group – Priority Planning**

Business Unit	What we DO today	What SHOULDN'T we do or be responsible for	What we need to be DOING in the future
ABDC	<ul style="list-style-type: none"> <li>Regulatory oversight</li> <li>Annual compliance audits</li> <li>Policies &amp; procedures and training support</li> <li>Support government audits/inspections</li> <li>Support consolidations, conversions and new builds</li> </ul>	<ul style="list-style-type: none"> <li>Manages FM Global inspections</li> <li>Escort non-security contractors in the warehouse</li> <li>Maintain all security systems including access card, key control, CCTV and alarm system</li> <li>Assists in counting and verification of inventory</li> </ul>	<ul style="list-style-type: none"> <li>Get more involved with state &amp; federal regulatory agencies in rulemaking process.</li> <li>Support QA/QC implementation</li> </ul>

**CSRA Responsibility Grid – by Business Unit / Function**

Business Unit / Division	FUNCTIONS			
	Regulatory	Diversion Control	Security/Investigations	Other / Non-regulatory Compliance
<b>MWI</b>	<ul style="list-style-type: none"> <li>Regulatory oversight</li> <li>Annual compliance audits</li> <li>Policies &amp; procedures and training support</li> <li>Support government</li> </ul>	<ul style="list-style-type: none"> <li>Audit the system (CMP) to identify and report suspicious orders of controlled substances and listed chemicals to DEA, as well as the known Your Customer due diligence</li> </ul>	<ul style="list-style-type: none"> <li>Investigations</li> <li>Oversight of physical security programs, including security system design, installation, management support and</li> </ul>	
<b>ABDC</b>	<ul style="list-style-type: none"> <li>Regulatory oversight w/ on-site CSRA Managers</li> <li>Annual compliance audits</li> <li>Policies &amp; procedures and training support</li> <li>Support government audits/inspections</li> <li>Support consolidations, conversions and new builds</li> <li>Support DIC licensing</li> <li>Customer license verification</li> </ul>	<ul style="list-style-type: none"> <li>Maintain and operate the system (CMP) to identify and report suspicious orders of controlled substances and listed chemicals to DEA</li> <li>Conduct Know Your Customer (KYC) due diligence investigations for new customer onboarding's</li> <li>Continuously monitor customer purchasing activities through a variety of analytical reports to detect "red flag" behavior</li> <li>Manage an outside consulting firm for the purpose of conducting in depth on-site customer inspections</li> <li>Assist legal in responding to inquiries and investigations by Federal and State regulators</li> <li>Provide support for physical audits</li> </ul>	<ul style="list-style-type: none"> <li>Investigations</li> <li>Inventory Adjustment Program</li> <li>Returns Program</li> <li>Contract Diversion</li> <li>GPS Program</li> <li>Supply Chain Security</li> <li>Product Integrity Program</li> <li>Oversight of physical security programs, including security system design, installation, management support and decommission; Tyco DataSource Program, EDATA Manager Program, and all security system vendor relationships and contracts</li> <li>Physical security policies and procedures and training support</li> </ul>	<ul style="list-style-type: none"> <li>COSTCO</li> <li>Oversight – auditing for CS handling</li> <li>Possibly implementation of self-audit process</li> </ul>

Examples

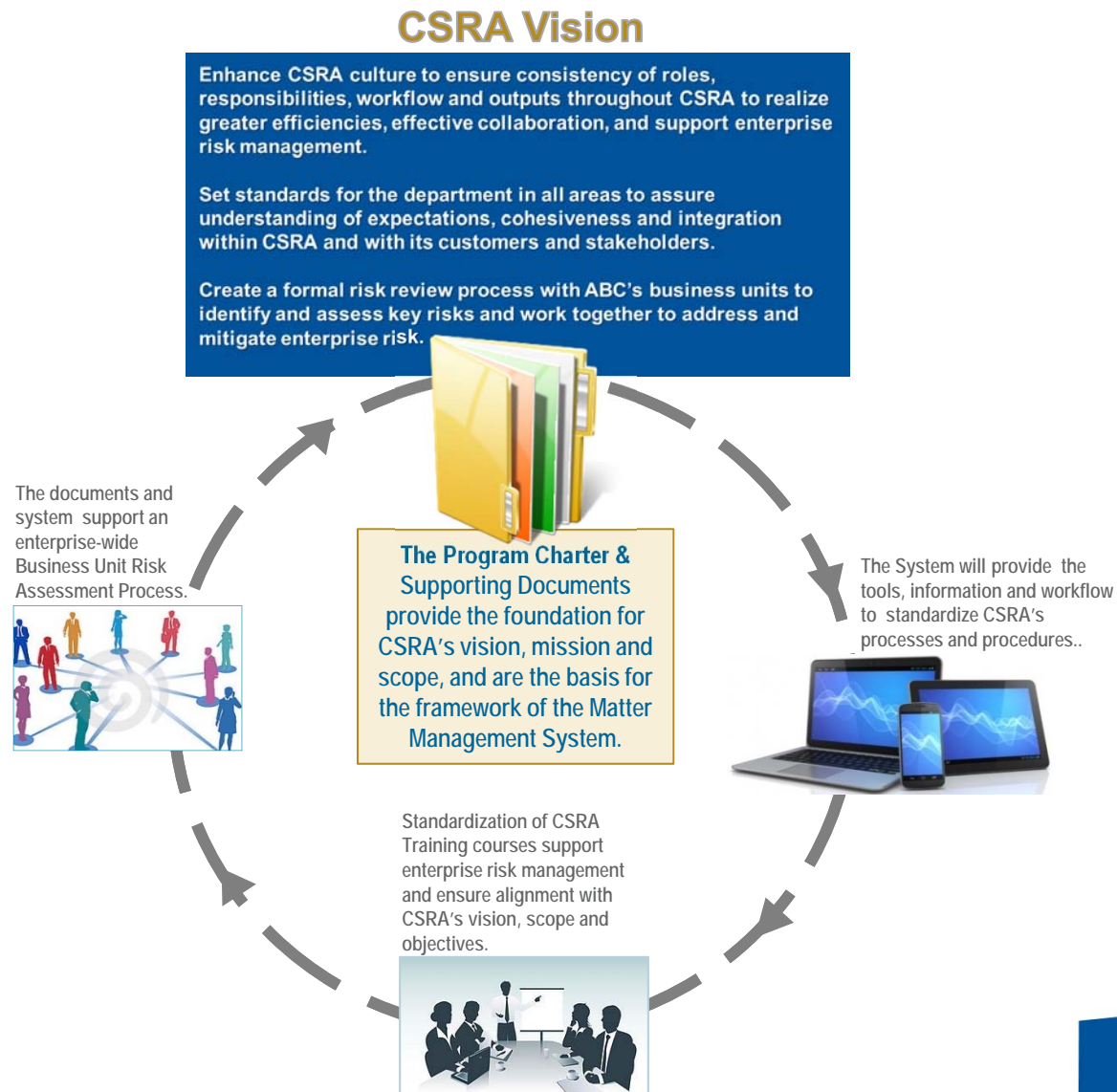
# Program Development – Business Unit Risk Assessment

- A detailed Risk Analysis process is being developed to assess risk and standardize risk ratings within the business units.
- CSRA will perform risk assessments and meet with business units - at a minimum on an annual basis - to provide a schedule of audits, investigations and projects for that year.
- Planning for the following year will also be reviewed to focus on specific risk areas where needed, and identify potential expenses and resources.
- Risk Assessments will be based on the budget cycle.

		KEY RISK INDICATORS															KEY MEASUREMENTS - A				ACTION/PLAN					
DRAFT		15	15	15	15	15	5	10	15	15	10	5-10-15	5	(10) NEW/15	10	15	Totals	-5	+5	+5	-5					
Business Unit Full Name	Subsidiaries/Groups	DEA-ABC	FCPA-Import/Export	Billing State/Federal Government	Medicaid - Medicare	PHI / HIPAA	Compounding	FDA-registered	Accreditation	Inventories	Diversification	Multiple Prof. & Site Licenses	Number of Associates	Multiple Locations	Recruitment process/structure or new associates	No CSRA on site	Misc	Past Audits Clear	Past Audits CAPAI CORREC	No CSRA visit last 12mth	CSRA visit last 12mth	ASD Healthcare Corp office only	15	ON-SITE AUDITS	TRAINING	VISITS
AmerisourceBergen Drug Corporation	American Health Packaging	X						X		X	X	X										Besse Medical Corp office only	15			
	Belco Generics																					HealthForward (part of Intrinsic)				
	Drug Distribution	15	15	15				5	10	15	15	10	15	5	10							SmartID (part of ION)				
	PharMEDium	X		X			X								15	10						ICS - Corp office only	40			
	Good Neighbor Pharmacy				15								5	5		10						Innomar Strategies (DC, HUB, NSG)	65			
	COSTCO				15					15	15	10	5	5			65		-5		-5	5	5			
	Pharmacy Healthcare Solutions	15		15		15			10	15	15	10	5	5		10	115				5		125			
AmerisourceBergen Animal Health	MWI											X	>500	X												
	ASD Healthcare Corp office only												10	5			15									
	Besse Medical Corp office only												5			10	15									
	HealthForward (part of Intrinsic)											???														
	SmartID (part of ION)											???														

Examples of Work in Progress

## CSRA Program Development – *It All Fits Together*





# Office of Compliance





## I. Overview of AmerisourceBergen's Office of Compliance

Contact Corporate Compliance:  
[compliance@amerisourcebergen.com](mailto:compliance@amerisourcebergen.com)

The Network (anonymous reporting):  
[www.tnwgrc.com/AmerisourceBergen](http://www.tnwgrc.com/AmerisourceBergen)

US/Canada - 800-241-568  
UK – 0808-234-1086  
All other locations – dial int'l access  
code, then toll-free at 800-241-5689



## I. AmerisourceBergen's Corporate Compliance Program

- We have a long-established and embedded **culture of compliance** throughout the entire company.
- A key component of our program is our **global Code of Ethics**, which meets U.S. federal sentencing guidelines and applies to all businesses.
- We provide a **robust training program** on ethics and compliance, incorporating desktop, classroom, and one-on-one training modules in multiple languages.
- We **monitor compliance** through numerous mechanisms.
- We encourage **reporting of potential non-compliance** (e.g., Hotline).
- We provide periodic **compliance newsletters/updates** to all associates.

## II. Interaction, Engagement and Oversight

- We maintain the Office of Compliance and the Office of Privacy which incorporate participation from Compliance and Privacy Representatives at each business unit allowing us to **set “tone from the top”/“tone from the middle”**.
- We conduct regular and broad-based **investigations and audits** of our businesses and compliance program.
- We have a comprehensive **escalation process** for reporting compliance incidents to management and the Board of Directors.
- We provide detailed **compliance reports to executive management** and the Audit and Corporate Responsibility Committee to ensure transparency.
- We have regularly scheduled meetings with executives and business leaders to **foster open communication about compliance** and regulatory matters.

### III. Key Compliance Topics for AmerisourceBergen

- Continue to strengthen our efforts to prevent, identify, and detect noncompliance with **global anti-bribery/anti-corruption laws and international trade/export laws**.
- Ensure that **new businesses**, such as MWI and PharMEDium, **are integrated** into our compliance program and meet appropriate legal, regulatory, quality and safety standards.
- Continue to evaluate and enhance our comprehensive **anti-drug diversion program** and controls relating to the distribution of controlled substances.
- Continue to focus on compliance with numerous and diverse **data privacy laws** applicable to our operation of a global business.

# CSRA Compliance Incident Reporting

Corporate Security Services

## The Network Call Reception/Assignment Process







# Global Business Resilience

## Emergency Preparedness

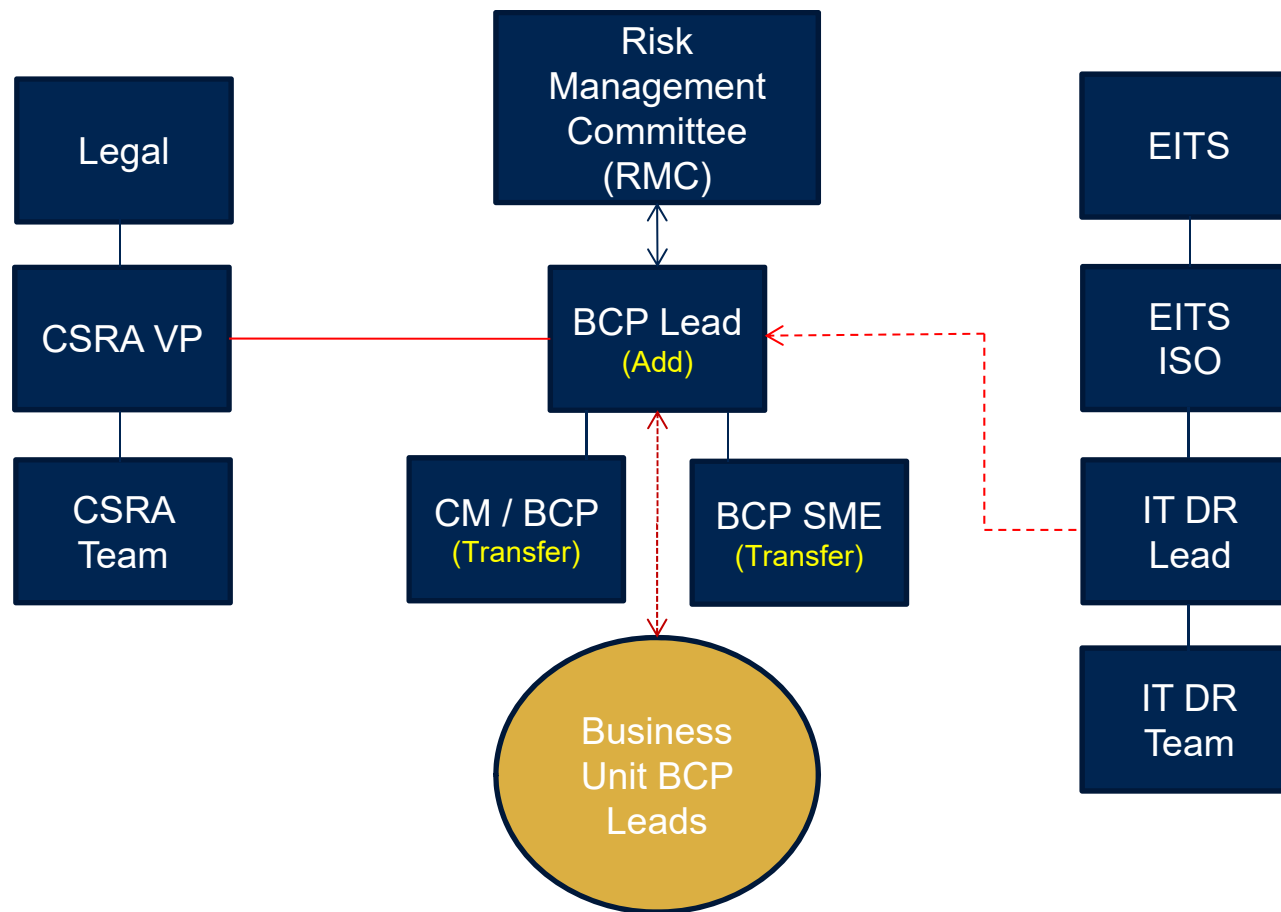


## Recommendations

- Designate and confirm accountability and responsibility for program implementation at an enterprise and business unit level.
- Formalize the Enterprise BCM Office and supplement it with additional resources with specific Business Unit experience.
- Develop and implement a standard enterprise BCM planning framework in line with industry leading standards and practices. Essential components of the framework include:
  - Program Governance: Policies, procedures, governance structures and processes
  - Development / Implementation: Risk Assessment & Business Impact Analysis (BIA), Recovery Strategies, and Documentation
  - Operation / Sustainability: Testing, Maintenance, Training and Awareness
- Develop and deliver standardized training to each member of the team to ensure consistency in program oversight and functional area implementation.
- A detailed report of the PwC Assessment findings will be distributed to each business unit and their respective responsible person(s) in efforts to drive the continued development of the BCM Program towards maturity while the enterprise BCM Office proposal is reviewed and considered for development.

## Business Continuity Program – Enterprise Governance Framework

[As Adopted by Risk Management Committee for Implementation Beginning FY17 (*modified*)]



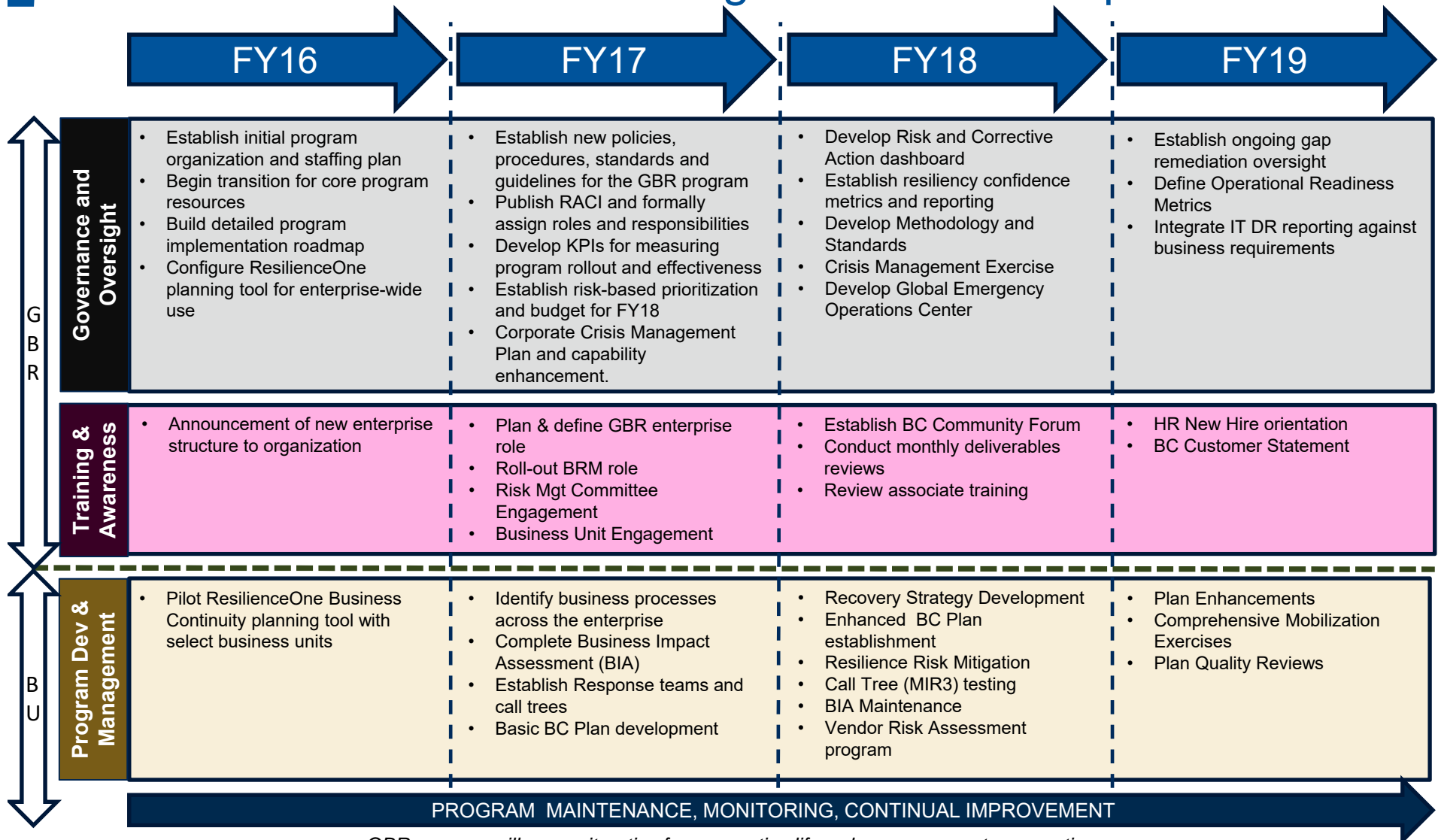
CSRA = Corporate Security & Regulatory Affairs

EITS = Enterprise IT

ISO = Information Security Office

DR = Disaster Recovery

# Global Business Resilience High-Level Roadmap



*GBR program pillars are iterative from an active lifecycle management perspective*

*Roadmap assumes constrained ramp-up in FY17 due to funding limitations for establishing the new organization*



# Functional Responsibilities – Current / Future

Program Function Name	Current Organization	Change	Future Function Name
BC Oversight committee	CSRA	Moves to GBR	GBR Steering Committee
BC Policies	CSRA	Moves to GBR	GBR Policies
Crisis Management	CSRA	Moves to GBR	Crisis Management
Business Impact Analysis	EITS	Moves to GBR	Business Impact Analysis
BU BC committee Member	EITS	Moves to GBR	GBR Steering Committee
Pandemic Policy & Plan	Risk	Moves to GBR	Pandemic Program Management
Technology Risk Assessment & Gap Mitigation	EITS	Transforms	Business Risk Assessment & Gap Mitigation
IT DR Policies (extract BC Policies)	EITS	Transforms	GBR Policies
IT Incident Management	EITS	No Change	
High Availability Design, Build, Test	EITS	No Change	
Disaster Recovery Design, Build, Test	EITS	No Change	
Global Emergency Operations Center (GEOC)	New	New	Global Emergency Operations (GEOC)



Moves to GBR



Remains/No change



Transforms



New Function  
AmerisourceBergen®

## Examples of Major Incidents that have impacted AmerisourceBergen

### ■ 2001

- Terrorist Attacks (9/11)–ABC Corporate
- Anthrax Episodes–ABDC

### ■ 2003

- Tornado–Houston, TX

### ■ 2005

- Hurricane Katrina–Houston, TX
- Hurricane Rita–Houston, TX

### ■ 2007

- Train Derailment–Brooks, KY
- Orlando DC DEA Registration Suspension

### ■ 2008

- Hurricane Ike–Houston, TX

### ■ 2009

- Ice Storm–Paducah, KY

### ■ 2010

- Tanker Truck-Train Accident–Brooks, KY

### ■ 2011

- Winter Storm – North/South/East Regions
- Tornadoes – Mississippi and Alabama
- Floods – Central United States
- Tornadoes – Missouri
- Hurricane Irene – East Region
- Tropical Storm Lee – East Region

### ■ 2012

- Dallas (Roanoke) Tornadoes
- ABCC Mississauga Data Center Fire
- Hurricane Isaac
- Tropical Storm Leslie
- Hurricane Sandy

### ■ 2013

- Severe Winter Weather – North/East Region
- Severe Winter Weather – All Regions
- ABC / ABDC System-wide Network Incident
- Boston Marathon Bombing

### ■ 2014

- Severe Winter Weather – 27 Named Winter Storms
- Tornadoes - Missouri
- Earthquake – Napa, CA
- Ferguson, MO – Riots
- Ebola Watch

### ■ 2015

- Severe Winter Weather – 27 Named Winter Storms
- Baltimore, MD - Riots
- Network / Phone Connectivity Loss – Denver, CO